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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,127	04/19/2004	Mitchell Kyle	44564.004	2311

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Intellectual Property Department
DEWITT ROSS & STEVENS, S.C.
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EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,127

Applicant(s)

KYLE, MITCHELL

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-13 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “to promote wound healing and to reduce pruritus” in claims 1 and 7 renders the claims indefinite. More specifically, it is unclear whether the pruritic condition must exist for wound healing to be promoted and vice versa, if each condition can be treated separately.

The term “non-medicinal carriers” in claims 1, 6, 7, 12 and 13 is a term that renders the claims indefinite. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what constitutes a non-medicinal carrier.

Claim 13 provides for “the use of an effective amount of zinc derivative and heparin derivative admixed with non-medicinal carriers” but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Lukas et al. (EP 12115 A1).

In claim 1, applicant claims “A composition to promote wound healing and to reduce pruritus resulted from insect bites, comprising a therapeutically effective amount of zinc derivative and glycosaminoglycan admixed with non-medicinal carriers.” Lukas et al. disclose applicant’s composition comprising a therapeutically effective amount of zinc derivative (ZnSO₄·7H₂O) and glycosaminoglycan (sodium heparin) admixed with carriers (methylparaben and propylparaben) (see abstract). It should be noted that claim 1 is a composition claim and the

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intended use of the composition does not add to the patentability of the claimed composition.

Furthermore, Lukas et al. composition contains the same ingredients (active ingredients and carriers) as applicant's composition and therefore should have the same effect of promoting wound healing and reducing pruritus resulted from insect bites, as applicant's composition.

Claim 2 which is drawn to specific glycosaminoglycans, is also anticipated by Lukas et al., since Lukas et al. composition also contain the same glycosaminoglycan (sodium heparin) (see abstract). Claim 6 is drawn to a composition according to claim 1, wherein said non-medicinal carriers is selected from the group consisting of carboxymethylcellulose, glycerin, methylparaben, polysorbate, propylparaben and water. Lukas et al. disclose applicant's composition of claim 6 comprising a therapeutically effective amount of zinc derivative ($\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$) and glycosaminoglycan (sodium heparin) admixed with carriers (methylparaben and propylparaben) (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peshoff (US 2002/0114847 A1) in combination with Edwards et al. (US 5,899,917).

In claim 1, applicant claims "A composition to promote wound healing and to reduce pruritus resulted from insect bites, comprising a therapeutically effective amount of zinc derivative and glycosaminoglycan admixed with non-medicinal carriers." In claim 2, applicant

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claims the composition according to claim 1, wherein said glycosaminoglycan is a heparin derivative. In claim 3 applicant claims the composition of claim 1, wherein said zinc derivative is zinc and said glycosaminoglycan is sodium heparin. Dependent claims 4-6 are drawn to compositions containing specific amounts of heparin and zinc oxide and specific non-medicinal carriers such including water.

Peshoff discloses a composition comprising an effective amount of a zinc derivative (zinc oxide oxide) (see claim 24, page 21 and 22). In addition, Peshoff discloses that zinc oxide promotes cleansing of wounds and decreases deterioration of existing wounds (see page 3, paragraph [0025]) and accelerates the healing of both chronic and acute wounds (see page 3, paragraph [0026]).

Edwards et al. disclose that heparin and its derivatives promote the healing of wounds (col. 27, lines 17-23).

The difference between applicant's claimed composition and the composition taught by Peshoff is that applicant also uses a heparin derivative in their composition and a non-medicinal carrier. However, Edwards et al. disclose that heparin and its derivatives promote the healing of wounds (col. 27, lines 17-23), and the use of a non-medicinal carriers such as water in said composition is common in the art.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Peshoff and Edwards et al., to have prepared a composition comprising a combination of a zinc derivative such as zinc oxide and a heparin derivative such as sodium heparin to be used to promote the healing of wounds, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More

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specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Peshoff and Edwards et al., to prepare a composition comprising a combination of a zinc derivative such as zinc oxide and a heparin derivative such as sodium heparin to be used to promote the healing of wounds, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Peshoff and Edwards et al., to promote the healing of wounds based on type and/or severity of the viral infection or activity. It should be noted that the use of specific amounts of zinc oxide and heparin derivative depends factors such as severity and type of the wound treated.

In claim 7, applicant claims "A method for promoting wound healing and reducing pruritus resulted from insect bites, comprising applying topically to the affected area an effective amount of zinc derivative and glycosaminoglycan composition admixed with non-medicinal carriers." Dependent claims 8-12 are drawn to methods involving the use of specific glycoaminoglycans, specific amounts of heparin and zinc oxide and specific non-medicinal carriers such including water.

Peshoff discloses a method for promoting wound healing, comprising applying topically to the affected area an effective amount of a composition comprising a zinc derivative (zinc oxide oxide) (see claim 24, page 21 and 22). In addition, Peshoff discloses that zinc oxide promotes cleansing of wounds and decreases deterioration of existing wounds (see page 3,

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paragraph [0025]) and accelerates the healing of both chronic and acute wounds (see page 3, paragraph [0026]).

Edwards et al. disclose that heparin and its derivatives promote the healing of wounds (col. 27, lines 17-23).

The difference between applicant's claimed method and the method taught by Peshoff is that applicant also uses a heparin derivative in their composition and a non-medicinal carrier. However, Edwards et al. disclose that heparin and its derivatives promote the healing of wounds (col. 27, lines 17-23), and the use of a non-medicinal carriers such as water in said composition is common in the art.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Peshoff and Edwards et al., to have used the method of Peshoff to promote the healing of wounds with a composition comprising a combination of a zinc derivative such as zinc oxide and a heparin derivative such as sodium heparin, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Peshoff and Edwards et al., to have use the method of Peshoff to promote the healing of wounds with a composition comprising a combination of a zinc derivative such as zinc oxide and a heparin derivative such as sodium heparin, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Peshoff and

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Edwards et al., to promote the healing of wounds based on type and/or severity of the viral infection or activity. It should be noted that the use of specific amounts of zinc oxide and heparin derivative depends factors such as severity and type of the wound treated.

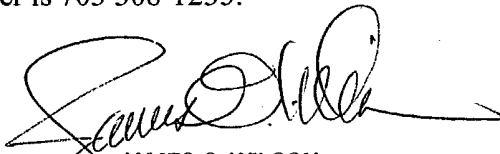
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

December 23, 2004.


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